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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,000	03/31/2004	**Chunlin Yang**	DEP-5286	1332

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,000	YANG ET AL.	
	Examiner	Art Unit	
	AGNES B. ROOKE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *15-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This FINAL office action is in response to the paper filed on 01/04/2008. The amendments to the claims are acknowledged.

Status of Claims

Claims 1-23 are pending.

Claims 1-14 are under consideration, Claims 15-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Objections Withdrawn

Objections to claims are withdrawn because of the amendments to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

In claim 1, the phrase "substantially uniformly distributed" is indefinite because it is not certain what is the level of uniformly distributed collagen in a graft. Also, no definition or indication of level is provided in the specification. Dependent claims 2-14

are included in this rejection because they do not further cure the deficiencies of the independent claims. Thus, clarification is required.

Applicants responded that the U.S. 5,231,169 refers to a "substantially uniform distribution" and conclude that because the prior art teaches such terms, further definition is not required in the instant application.

Examiner responds that upon examination of the instant application, the phrase "substantially uniformly distributed" is not definite in the instant application because the specification does not define how uniform the distribution must be such that it is "substantially" uniform. Clarification of the term is required.

In claim 4, the phrase "thrombin derived peptides" is indefinite since there is no definition in the specification that would define or explain such terms.

Applicants responded that other patents U.S. 5,355,664 and 5,500,412 used such phrases and thus the phrase in the instant application is understood to have its common meaning.

Examiner responds that the phrase is indefinite because it is uncertain what the "thrombin derived peptides" looks like. For example, a single amino acid from the thrombin structure that is incorporated into another peptide would be a thrombin derived peptide, because it would comprise one amino acid from the thrombin structure. Thus, examiner cannot ascertain the metes and bounds of the phrase as presented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 9, 11, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. U.S. 2002/0183855.

Yamamoto et al. teach porous matrix that comprises mineralized fibrillar insoluble collagen (See [0014]) and to form a porous fixed tissue repair matrix, the mineralized biopolymer fibers are mixed with a binder. (See [0024]). The binders include gelatin, carboxymethylcellulose, and hyaluronic acid. (See [0026]). (claims 1, 2, and 14).

The matrix material can be combined with an osteogenic material, such as autogenous bone or autologous aspirated bone marrow, or osteoinductive bone growth factors, BMP's, or other growth factors. (See [0037]). (instant claim 3, 4, 5, 8, and 9 where sodium hyalurane is a form of hyaluronic acid).

The mineralized collagen will be in the range from about 0.1 to 10 weight percent. (See [0017]) (instant claims 6, 11, 12). Yamamoto et al. also teach that the amount of collagen present in the mineralized product will generally be from about 95% to 30% based on the weight of collagen fibers exclusive to the binder. (See [0023]) (instant claim 11).

Applicants responded that the instant invention refers to "a fluid biocompatible carrier" and that Yamamoto et al. do not describe such a carrier. Further, they state that the matrix in Yamamoto et al. is not a flowable composition.

Examiner responds that a porous matrix could be considered a fluid biocompatible carrier, for example, since the matrix can be easily hydrated when placed in a fluid. Also, instant claims do not require that the bone graft be flowable. The instant claims do require that the composition be suitable for administration via a cannula and this is taught by Yamamoto et al (see page 3, [0034]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 6, 7, 10, and 13 under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. U.S. 2002/0183855 in view of Silver et al. U.S. 5,532,217 is maintained.

The teachings of Yamamoto are disclosed above where they do not teach diameters for collagen fibers.

Silver et al. in column 2, lines 19-25 teach a bone replacement structure that has demineralized matrix and where the collagen fibers can have diameter of less than a micron and up to several millimeters. (claims 7, 10, and 13 of the instant invention).

Also, the collagen fibers with such diameters will form mineralized intact collagen fibers with subfibrillar substructure.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a graft that has properties as taught by Yamamoto et al. and to have collagen particles with diameters as disclosed by Silver et al. because the collagen fibers with diameters of the instant invention will work effectively in a graft design and it will successfully form an intact collagen fibers with subfibrillar structure in the are of interest, and thus such a graft would be predictable to work successfully with this particle size.

Applicants responded that the instant invention is directed to a flowable composition having a fluid biocompatible carrier.

Examiner responds that the prior art, as presented above, teaches the instant composition as comprising a fluid biocompatible composition. Further, there are no limitations in the instant claims, as presented, to reflect that the instant invention be flowable. Further, since all the limitations are taught in the prior art, it is expected that both compositions will have the same chemical and physical properties, since they have the same structures.

Conclusion

No claims are allowed.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished applications is available through Private PAIR or Public PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR

/Kathleen Kerr Bragdon/

Supervisory Patent Examiner, Art Unit 1656